Complete Summary

GUIDELINE TITLE

Glucose control and progression of diabetic nephropathy.

BIBLIOGRAPHIC SOURCE(S)

Nicholls K. Glucose control and progression of diabetic nephropathy. Nephrology 2006 Apr;11(S1):S109-13.

Nicholls K. Glucose control and progression of diabetic nephropathy. Westmead NSW (Australia): CARI - Caring for Australasians with Renal Impairment; 2005 Sep. 9 p. [13 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

- Chronic kidney disease
- Diabetes mellitus, Type 1 and Type 2
- Diabetic nephropathy

GUIDELINE CATEGORY

Management
Treatment

CLINICAL SPECIALTY

Endocrinology
Family Practice
Internal Medicine
Nephrology
Nutrition
Pediatrics

INTENDED USERS

Dietitians
Physicians

GUIDELINE OBJECTIVE(S)

To review the available clinical evidence pertaining to the glucose control and progression of diabetic nephropathy

TARGET POPULATION

Adults and children with chronic kidney disease and Type 1 and Type 2 diabetes mellitus

INTERVENTIONS AND PRACTICES CONSIDERED

Establishment of target levels for optimal glycaemic control

- Glycosylated haemoglobin (HbA1c)
- Preprandial blood glucose level

MAJOR OUTCOMES CONSIDERED

- Glycosylated haemoglobin (HbA1c)
- Preprandial blood glucose level
- Progression of diabetic nephropathy

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Databases searched: The Cochrane Renal Group Specialized Register was searched for randomized controlled trials relating to the prevention of progression of kidney disease in people with diabetes mellitus Type 1 and Type 2. Specific interventions included antihypertensive therapies, angiotensin converting enzyme (ACE) inhibitors, A II receptor antagonists, calcium channel blockers, dietary protein restriction and glucose control, and interventions to control hypercholesterolemia and hyperlipidemia.

Date of search: 16 December 2003.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence

Level I: Evidence obtained from a systematic review of all relevant randomized controlled trials (RCTs)

Level II: Evidence obtained from at least one properly designed RCT

Level III: Evidence obtained from well-designed pseudo-randomized controlled trials (alternate allocation or some other method); comparative studies with concurrent controls and allocation not randomized, cohort studies, case-control studies, interrupted time series with a control group; comparative studies with historical control, two or more single arm studies, interrupted time series without a parallel control group

Level IV: Evidence obtained from case series, either post-test or pretest/post-test

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Comparison with Guidelines from Other Groups
Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Recommendations of Others. Recommendations regarding glucose control and progression of diabetic nephropathy from the following groups were discussed: Kidney Disease Outcomes Quality Initiative (2004), UK Renal Association, Canadian Society of Nephrology, European Best Practice Guidelines, American Diabetes Association, American Diabetes Association (Revision 2004), American Association of Clinical Endocrinology, Canadian Diabetes Association (2003), and Australian Paediatric Endocrinology Group (2005).

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Definitions for the levels of evidence (I–IV) can be found at the end of the "Major Recommendations" field.

Guidelines

a. In both Type 1 and Type 2 diabetics glycosylated haemoglobin (HbA1c) should be maintained at or < 7% for primary prevention of diabetic nephropathy, and for prevention of progression from microalbuminuria to overt nephropathy. (Level I evidence for Type 1 diabetes – moderate volume; Level I evidence for Type 2 diabetes – small volume)
b. Optimal glycaemic control - preprandial blood glucose 4.4–6.7 mmol/L and HbA1c < 7% carries increased risk of hypoglycaemia. (There is no evidence that tight control in Type 2 diabetics with overt nephropathy will alter outcome)

Suggestions for Clinical Care

(Suggestions are based on Level III and IV sources)

- The Australian Diabetes Association is attempting to standardize HbA1c assays nationally. Some older assays are falsely elevated by carbamylated Hb in chronic kidney disease (CKD).
- The risk of hypoglycaemia can be minimised by frequent blood glucose monitoring with appropriate intervention (AACE).
- There is evidence that renal damage rarely occurs in patients with either Type 1 or Type 2 diabetes if HbA1c is < 7.5% and postprandial blood glucose is <

10.1 mmol/L. Data from the Joslin Clinic (Type 1) suggests that a low incidence rate of diabetic nephropathy occurs when HbA1c < 8.0%. Lower levels of HbA1c may be required for macrovascular protection.

- A major limitation of the available data is that they do not identify the optimum level of control for particular patients, as there are individual differences in the risks of hypoglycaemia, weight gain, and other adverse effects.
- It is unclear how different components of multifactorial interventions (e.g., educational interventions, glycaemic targets, lifestyle changes, and pharmacological agents) contribute to the reduction of complications.
- There are no clinical trial data available for the effects of glycaemic control in patients with advanced complications, the elderly (> 65 years of age), or children < 13 years.
- In the United Kingdom Prospective Diabetes Study (UKPDS) and the Diabetes Control and Complications Trial (DCCT), intensive control trebled the risks of hypoglycaemia and increased weight gain.
- Epidemiological analyses suggest that there is no lower limit of A1c at which further lowering does not reduce risk of complications. However, the absolute risks and benefits of lower targets are unknown.
- The risks and benefits of an A1c goal of < 6% are currently being tested in an ongoing study (ACCORD = Action to Control Cardiovascular Risk in Diabetes) in Type 2 diabetes.
- Elevated post challenge (2-h oral glucose tolerance test) glucose values have been associated with increased cardiovascular risk independent of fasting plasma glucose (FPG) in some epidemiological studies. Postprandial plasma glucose (PPG) levels > 7.8 mmol/L are unusual in non-diabetics, although large evening meals can be followed by plasma glucose values up to 10 mmol/L.
- The longer patients can maintain a target HbA1c level of 7.0%, which is achievable with current methods, the greater their protection from nephropathy.

Definitions:

Levels of Evidence

Level I: Evidence obtained from a systematic review of all relevant randomized controlled trials (RCTs)

Level II: Evidence obtained from at least one properly designed RCT

Level III: Evidence obtained from well-designed pseudo-randomized controlled trials (alternate allocation or some other method); comparative studies with concurrent controls and allocation not randomized, cohort studies, case-control studies, interrupted time series with a control group; comparative studies with historical control, two or more single arm studies, interrupted time series without a parallel control group

Level IV: Evidence obtained from case series, either post-test or pretest/post-test

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate management of glucose control to prevent the progression of diabetic nephropathy in patients with chronic kidney disease

POTENTIAL HARMS

- Optimal glycaemic control - preprandial blood glucose 4.4–6.7 mmol/L and HbA1c < 7% carries increased risk of hypoglycaemia.
- In the United Kingdom Prospective Diabetes Study and the Diabetes Control and Complications Trial, intensive control trebled the risks of hypoglycaemia and increased weight gain.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2006 Apr

GUIDELINE DEVELOPER(S)

Caring for Australasians with Renal Impairment - Disease Specific Society

SOURCE(S) OF FUNDING

Industry-sponsored funding administered through Kidney Health Australia

GUIDELINE COMMITTEE

Not stated

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Author: Kathy Nicholls

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

All guideline writers are required to fill out a declaration of conflict of interest.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the Caring for Australasians with Renal Impairment Web site.

Print copies: Available from Caring for Australasians with Renal Impairment, Locked Bag 4001, Centre for Kidney Research, Westmead NSW, Australia 2145

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- The CARI guidelines. A guide for writers. Caring for Australasians with Renal Impairment. 2009 Aug. 6 p.

Electronic copies: Available from the Caring for Australasians with Renal Impairment (CARI) Web site.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI Institute on May 11, 2008.

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